DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the HRSA-Supported Women's Preventive Services Guidelines Relating to Screening for Diabetes in Pregnancy and Screening for Diabetes After Pregnancy

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: A Federal Register notice published on November 3, 2022, detailed and sought public comment on recommendations under development by the Women's Preventive Services Initiative (WPSI), regarding updates to the HRSA-supported Women's Preventive Services Guidelines (Guidelines). The proposed updates specifically related to (1) Screening for Diabetes in Pregnancy and (2) Screening for Diabetes after Pregnancy. WPSI convenes health professionals to develop draft recommendations for HRSA's consideration. Three comments were received and considered as detailed below. On December 30, 2022, HRSA accepted as final WPSI's recommended updates to the (1) Screening for Diabetes in Pregnancy and (2) Screening for Diabetes after Pregnancy guidelines. Under applicable law, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage must include coverage, without cost sharing, for certain preventive services, including those provided for in the HRSA-supported Guidelines. The Departments of Labor, Health and Human Services, and the Treasury have previously issued regulations describing how group health plans and health insurance issuers apply the coverage requirements. Please see https://www.hrsa.gov/womens-guidelines for additional information.

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone: (301) 443-8283, email: wellwomancare@hrsa.gov.

SUPPLEMENTARY INFORMATION: Under the Patient Protection and Affordable Care

Act, Public Law 111-148, the preventive care and screenings set forth in the Guidelines are

required to be covered without cost-sharing by certain group health plans and health insurance

issuers. HRSA established the Guidelines in 2011 based on expert recommendations by the

Institute of Medicine, now known as the National Academy of Medicine, developed under a

contract with the Department of Health and Human Services. Since 2016, HRSA has funded

cooperative agreements with the American College of Obstetricians and Gynecologists (ACOG)

for the Women's Preventive Services Initiative (WPSI), to convene a coalition representing

clinicians, academics, and consumer-focused health professional organizations to conduct a

rigorous review of current scientific evidence, solicit and consider public input, and make

recommendations to HRSA regarding updates to the Guidelines to improve adult women's health

across the lifespan. HRSA then determines whether to support, in whole or in part, the

recommended updates to the Guidelines.

WPSI incudes an Advisory Panel and two expert committees, the Multidisciplinary Steering Committee and the Dissemination and Implementation Steering Committee, which are comprised of a broad coalition of organizational representatives who are experts in disease prevention and women's health issues. With oversight by the Advisory Panel, and with input from the Multidisciplinary Steering Committee, WPSI examines the evidence to develop new (and update existing) recommendations for women's preventive services. WPSI's Dissemination and Implementation Steering Committee takes HRSA-approved recommendations and disseminates them through the development of implementation tools and resources for both patients and practitioners.

WPSI bases its recommended updates to the Guidelines on review and synthesis of existing clinical guidelines and new scientific evidence, following the National Academy of Medicine standards for establishing foundations for and rating strengths of recommendations, articulation of recommendations, and external reviews. Additionally, HRSA requires that WPSI incorporate processes to assure opportunity for public comment, including participation by patients and consumers, in the development of the updated Guidelines.

WPSI proposed and HRSA has accepted recommended updates to the Guidelines relating to Screening for Diabetes in Pregnancy and Screening for Diabetes after Pregnancy as detailed below:

(1) Screening for Diabetes in Pregnancy:

The current "Screening for Gestational Diabetes Mellitus" title is now revised to read "Screening for Diabetes in Pregnancy" and the clinical recommendation is now revised to state: "The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) to prevent adverse birth outcomes. WPSI recommends screening pregnant women with risk factors for type 2 diabetes or GDM before 24 weeks of gestation—ideally at the first prenatal visit."

(2) <u>Screening for Diabetes after Pregnancy:</u>

The current "Screening for Diabetes Mellitus after Pregnancy" title is now revised to read "Screening for Diabetes after Pregnancy" and the clinical recommendation is now revised to state: "The WPSI recommends screening for type 2 diabetes in women with a history of gestational diabetes mellitus (GDM) who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4–6 weeks postpartum. Women who were not screened in the first year postpartum or those with a negative initial postpartum screening test

result should be screened at least every 3 years for a minimum of 10 years after pregnancy. For those with a positive screening test result in the early postpartum period, testing should be repeated at least 6 months postpartum to confirm the diagnosis of diabetes regardless of the type of initial test (e.g., fasting plasma glucose, hemoglobin A1c, oral glucose tolerance test). Repeat testing is also indicated for women screened with hemoglobin A1c in the first 6 months postpartum regardless of whether the test results are positive or negative because the hemoglobin A1c test is less accurate during the first 6 months postpartum."

Discussion of Recommended Updated Guidelines

Screening for Diabetes in Pregnancy:

WPSI recommended three updates to the Guideline on Screening for Gestational Diabetes Mellitus. The first change is a revision to the title of the Guideline from "Screening for Gestational Diabetes Mellitus" to "Screening for Diabetes in Pregnancy." This change to the title was made for consistency with the clinical recommendation, which includes screening for gestational diabetes and screening for preexisting diabetes, as the previous title described a more limited scope in screening. The second update recommended by WPSI is to change language in the second sentence of the recommendation from "diabetes mellitus" to "type 2 diabetes or GDM." This change reflects that "diabetes mellitus" is commonly described as type 2 diabetes. Third, WPSI modified the recommendation by relocating the information on specific types of screening to the Implementation Considerations section of the Guideline. The existing Guideline recommends the 2-step approach, because of its high sensitivity and specificity. In its recommended update, WPSI continues to recommend the 2-step approach, but has relocated it to the Implementation Considerations section, and added the 1-step approach to the list of screening modalities in the Implementation Considerations section, because both approaches are acceptable screening tests based on studies described in the updated 2021 United States Preventive Services

Task Force evidence review. Both the 1-step and 2-step screening modalities are within the scope of this Guideline.

Screening for Diabetes After Pregnancy:

WPSI also recommended five updates to the Guideline on Screening for Diabetes Mellitus After Pregnancy. The first change is a revision to the title of the Guideline, from "Screening for Diabetes Mellitus After Pregnancy" to "Screening for Diabetes After Pregnancy." This change was made because "diabetes mellitus" is more commonly described as diabetes. Second, WPSI recommended removing the reference to Table 1, "Preferred Testing Strategy Based on Postpartum Timeframe" based upon feedback from the clinical community, noting that the table might be confusing and could be simplified in written format, and recommended including this information in narrative form. Third, WPSI recommended screening for "women who are not screened in the first year postpartum" and "women with a positive screening test result in early postpartum." This recommendation was added to ensure screening for women who were not screened postpartum for various reasons (e.g., scheduling, lack of transportation, availability of testing, etc.), and to reflect that universal screening for women with a history of GDM is more appropriate than risk-based screening because the risk of developing type 2 diabetes is high among all such individuals. Fourth, WPSI recommended adding new language to recommend repeat testing after 6 months postpartum to confirm a positive test result from the early postpartum period. Fifth, WPSI recommended adding new language to the Guideline explaining that hemoglobin A1c tests conducted within the first 6 months postpartum should be repeated because the test is less accurate when conducted during the first 6 months postpartum. Screening for type 2 diabetes after pregnancy as described in this Guideline, including follow-up diabetes screening testing, is within the scope of this Guideline.

A Federal Register notice published on November 3, 2022 sought public comment on these

proposed updates (87 FR 66310).¹ WPSI considered all public comments as part of its deliberative process and provided the comments to HRSA for its consideration. A total of three respondents provided comments during the public comment period. One commenter suggested that the word, "all" be added in front of "pregnant women" in the first sentence of the recommendation on Screening for Diabetes in Pregnancy. This comment was not accepted as the current wording already pertains to all individuals to which it applies. The remaining comments did not specifically address the recommended proposed updates. WPSI also removed the parenthetical description of the early postpartum period "(i.e., 4-6 weeks postpartum)" to better align with medical evidence.

After consideration of public comment, WPSI submitted the recommended updates for (1) Screening for Diabetes in Pregnancy and (2) Screening for Diabetes after Pregnancy as detailed above. On December 30, 2022, the HRSA Administrator accepted WPSI's recommendations and, as such, updated the Women's Preventive Services Guidelines. Nongrandfathered group health plans and health insurance issuers offering group or individual health insurance coverage must cover without cost-sharing the services and screenings listed on the updated Women's Preventive Services Guidelines for plan years (in the individual market, policy years) that begin 1 year after this date. Thus, for most plans, this update will take effect for purposes of the section 2713 coverage requirement in 2024. Additional information regarding the Women's Preventive Services Guidelines can be accessed at the following link: https://www.hrsa.gov/womens-guidelines.

Authority: Section 2713(a)(4) of the Public Health Service Act, 42 U.S.C. 300gg-13(a)(4).

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 $^{^1 \}it See \ https://www.federalregister.gov/documents/2022/11/03/2022-23860/notice-of-request-for-public-comment-on-two-draft-recommendations-to-update-the-hrsa-supported.$

Carole Johnson,

Administrator.

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